

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k071597

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation

Manufacturer: Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714

Contact Information: Siemens Healthcare Diagnostics Inc.
P.O. Box 6101
Newark, DE 19714
Attn: Pamela A. Jurga
Tel: 302-631-8891

Date of Preparation: May 8, 2008

2. Device Name / Classification

- Dimension Vista® AFP reagent cartridge/ Class II
- Dimension Vista® LOCI 5 calibrator/ Class II

3. Identification of the Predicate Device

- Abbott AxSYM® AFP Method (P820060/S019)
- Beckman Access AFP Calibrators on the Access® Immunoassay System (K981354).

FDA Guidance Document(s):

- "Bundling Multiple Devices or Multiple Indications in a Single Submission"- 11/26/2003
- "Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable - Guidance for Sponsors, Institutional Review Boards, Clinical Investigators and FDA Staff "- 4/25/2006

4. Device Description(s):

Method

The AFP method is a homogeneous, sandwich chemiluminescent immunoassay based on LOCI™ technology. The LOCI™ reagents include two synthetic bead reagents and a biotinylated anti-AFP monoclonal antibody fragment. The first bead reagent (Chemibeads) is coated with an anti-AFP monoclonal antibody and contains chemiluminescent dye. The second bead reagent (Sensibeads) is coated with streptavidin and contains a photosensitizer dye. Sample is incubated with biotinylated antibody and Chemibeads to form bead-AFP-biotinylated antibody sandwiches. Sensibeads are added and bind to the biotin to form bead-pair immunocomplexes. Illumination of the complex at 680 nm generates singlet oxygen from Sensibeads which diffuses into the Chemibeads, triggering a chemiluminescent reaction. The resulting signal is measured at 612 nm and is a direct function of the AFP concentration in the sample.

Calibrator

The LOCI 5 Calibrator is a liquid multi-analyte product containing AFP from human cord serum. An additional analyte (CEA from human tissue culture) is contained in the product and will be included in the submission to FDA with its respective method. The kit consists of ten vials, two each of five levels containing 2 mL per vial. Description of the manufacturing, value assignment and stability testing processes are provided.

5. Device Intended Use:

Method

The AFP method is an *in vitro* diagnostic test for the quantitative measurement of alpha-fetoprotein in human on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

Calibrator

For the calibration of Alpha-Fetoprotein (AFP) method on the Dimension Vista® System.

6. Medical device to which equivalence is claimed:

Substantial Equivalence:

These products are substantially equivalent to other AFP test systems, such as the Abbott AxSYM® AFP Method (P820060/S019) and calibrators; Beckman Access AFP Calibrators on the Access® Immunoassay System (K981354).

Comparison to Predicate Device:

The proposed Dade Behring Dimension Vista® AFP method and the predicate Abbott AxSYM® AFP method are both *in vitro* diagnostic immunoassays intended for the measurement of alpha-fetoprotein (AFP) as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

The Dade Behring Dimension Vista® LOCI 5 calibrator and the predicate Beckman Access AFP Calibrators are both calibrators intended to calibrate their associated AFP methods.

A comparison summary of the features of the products is included in the following table.

Method:

Similarities		
Item	Device	Predicate
Intended Use	The AFP method is an in vitro diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum on the Dimension Vista® System. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.	AxSYM AFP is a Microparticle Enzyme Immunoassay (MEIA) for the quantitative determination of alpha-fetoprotein (AFP) in: <ol style="list-style-type: none"> 1. Human serum or plasma to aid in the management of patients with non-seminomatous testicular cancer.
Standardization	Traceable to the World Health Organization (WHO) Reference preparation for human AFP (72/225).	Traceable to the World Health Organization (WHO) Reference preparation for human AFP (72/225).
Measurement method	Chemiluminescent: Homogenous sandwich immunoassay based on LOCI™ technology	Microparticle Enzyme Immunoassay (MEIA) technology
Differences		
Item	Device	Predicate
Intended Use	Same as above	for the quantitative determination of alpha-fetoprotein (AFP) in: Human serum, plasma and amniotic fluid at 15 to 21 weeks gestation to aid in the detection of fetal open neural tube defects (NTD). Test results when used in conjunction with ultrasonography or

		amniography are a safe and effective aid in the detection of fetal open NTD.
Measuring Range	0.5– 1000.0 ng/mL	0.4–350.0 ng/mL
Sample Types	Serum	Serum, plasma Amniotic fluid
Sample Size	2 uL	58 uL

Calibrator:

Similarities		
Item	Device	Predicate
Intended Use	For the calibration of Alpha-Fetoprotein (AFP) method on the Dimension Vista® system.	The Access AFP Calibrators are intended to calibrate the Access AFP assay for the quantitative determination of AFP levels in human serum, using the Access Immunoassay System.
Traceability	AFP- World Health Organization (WHO) Reference Preparation 72/225	AFP- World Health Organization (WHO) Reference Preparation 72/225
Matrix	BSA-based matrix	BSA-based matrix
Preparation	Liquid: Provided ready to use.	Liquid: Provided ready to use.
Differences		
Item	Device	Predicate
Target Concentrations AFP	Level 1 (CAL A): 0 ng/mL Level 2 (CAL B): 8 ng/mL Level 3 (CAL C): 100 ng/mL Level 4 (CAL D): 500 ng/mL Level 5 (CAL E): 1050 ng/mL	Level 1 : 0 ng/mL Level 2: 2.5 ng/mL Level 3 5 ng/mL Level 4 25 ng/mL Level 5: 100 ng/mL Level 6: 500 ng/mL Level 7: 3000 ng/mL
Storage	Store at 2 to 8°C.	Store at 2 to 10°C.

Comments on Substantial Equivalence:

Method

The Dade Behring Dimension Vista® AFP method and the predicate Abbott AxSYM® AFP method are both *in vitro* diagnostic immunoassays intended for the measurement of alpha-fetoprotein (AFP)

as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

Comparative data for human serum samples demonstrate good analytical and clinical agreement between the methods including the split sample method comparison described below:

A split sample method comparison demonstrated good agreement between the Dade Behring Dimension Vista® AFP method and the predicate Abbott AxSYM® AFP method following CLSI Approved Guideline for Method Comparison and Bias Estimation Using Patient Samples; EP9-A2.

Comparative Method	Slope	Intercept ng/mL	Correlation	
			Coefficient	n
AxSYM® AFP	0.93	0.1	0.995	317

AxSYM® is a registered trademark of Abbott Laboratories, Abbott Park, Ill 60064 USA

The method used to fit the linear regression line was Passing-Bablok.
The range of 317 values in the correlation study was 0.97 – 881.24 ng/mL.

Calibrator

The Dade Behring Dimension Vista® LOCI 5 calibrator and the predicate Beckman Access AFP Calibrators are both calibrators intended to calibrate their associated AFP methods.

Conclusion:

The Dade Behring Dimension Vista® AFP method and the predicate Abbott AxSYM® AFP method (P820060/S019) are substantially equivalent based on their intended use and performance characteristics as described above. The calibrator products, the Dade Behring Dimension Vista® LOCI 5 calibrator and the predicate Beckman Access AFP calibrators are also substantially equivalent in its design and intended use with their respective assay systems (K981354).



Pamela A. Jurga
Regulatory Affairs and Compliance Manager
May 8, 2008



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics Inc.
c/o Ms. Pamela A Jurga
Regulatory Affairs and Compliance Manager
P.O. Box 6101, M/S 514
Newark, DE 19714-6101

JUN - 4 2008

Re: k071597

Trade/Device Name: Dimension Vista® AFP reagent cartridge
Dimension Vista® LOCI 5 calibrator
Regulation Number: 21 CFR 866.6010
Regulation Name: Tumor-associated antigen immunological test system
Regulatory Class: Class II
Product Code: LOJ, JIX
Dated: May 28, 2008
Received: May 29, 2008

Dear Ms. Jurga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The

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FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Becker, Jr.", with a stylized flourish at the end.

Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071597

Indications For Use:

The AFP method is an *in vitro* diagnostic test for the quantitative measurement of alpha-fetoprotein in human serum on the Dimension Vista® system. Measurements of alpha-fetoprotein are used as an aid in managing non-seminomatous testicular cancer when used in conjunction with physical examination, histology/pathology, and other clinical evaluation procedures.

Prescription Use √
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

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Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071597

Dade Behring Inc.
Dimension Vista® AFP Method and LOCI 5 Calibrator
Updated 510(k) Premarket Notification – k071597

Indications for Use

Device Name:

Dimension Vista® LOCI 5 Calibrator

Indications for Use:

For the calibration of the Alpha-Fetoprotein (AFP) method on the Dimension Vista® System.

Prescription Use ✓
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Evaluation and Safety

2007 K071597